



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-63

July 17, 1998

Mr. Michael Miller
President, Ravelco, Inc.
4118 Montrose Court
Orlando, Florida 32812

Dear Mr. Miller:

During an inspection of your firm on January 23, 1998, FDA Investigator Jose R. Rodriguez found that your firm is manufacturing and marketing Mountain Magic Herbal Remedy, in two forms: 16 oz. bottle of an Herbal Tea and packaged as a Dried Herbal Mix.

Labeling claims include:

- Mountain Magic Herbal Remedy (Rene Caisse's original formula) - cures throat, lung, ovarian and prostate cancer, AIDS, lupus, chronic fatigue syndrome and improves the conditions suffered by patients with multiple sclerosis and Alzheimers.

Based on these claims the product is a drug as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). This product is also a "new drug" [Section 201(p) of the Act] because it is not generally recognized as safe and effective for its intended uses [Section 505(a) of the Act].

The drug is misbranded because its labeling is false and misleading. It suggests that the drug is safe and effective for its intended use when this has not been established [Section 502(a) of the Act]. The labeling fails to bear adequate directions for use [Section 502(f)(1) of the Act].

Mr. Michael Miller

Page 2

July 17, 1998

The same claims appear in your web pages, including: a cure for cancer, lupus, AIDS, chronic fatigue and other illnesses, which further establish that Mountain Magic Herbal Remedy is intended for use as a drug.

This letter is not intended to be an all inclusive review of all labeling or products marketed by your firm. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We are also aware of additional products with unsubstantiated claims appearing on your Internet web pages. Testimonial statements included in your printed material or on the Internet, claiming that Mountain Magic Herbal Tea or Kombucha Tea, cures cancer and other serious diseases further demonstrates that you intend these products to be used as drugs.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement actions being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the correction will be implemented.

Your reply should be sent to the Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, Attn: Martin E. Katz, Compliance Officer, telephone no. (407) 475-4729.

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas D. Tolen". The signature is fluid and cursive, with a large loop at the end.

Douglas D. Tolen
Director, Florida District